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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| DUTT, ADITI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/602,823 | LACHARRIERE ET AL. | |
| | Examiner | Art Unit | |
| | Aditi Dutt | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *39,40,45,46 and 64-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38, 41-44, 47-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *25 June 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

1. The amendment of 25 June 2003 for specification has been received and acknowledged in full.

### *Election with traverse*

2. Applicant's election with traverse of Group I, claims 1-63, and the election of capsaicin as the species for prosecution, in the reply filed on July 17, 2006 is acknowledged.

3. The traversal is on the ground(s) that: (i) the kit is a "fundamental part of all other aspects of the claimed subject matter and accordingly provides **unity of invention**" and, therefore, the entire invention could be searched without serious burden on the Examiner; (ii) restriction requirement states that inventions should be "independent and distinct", instead of "only distinct". This is not found persuasive because Groups I-II are restricted properly as they comprise patentably distinct inventions, wherein the method of Group I and the product of Group II are distinct. The two Groups are only related as product and process of use. The compositions present in the kit can be used in other materially different assays, such as cell culture assays and treatment of pain. Again, as stated on page 3 of the previous Office Action, since the searches for the method and the product are not co-extensive and the subject matter is divergent, the search and

examination of both the inventions in one patent application would impose undue search burden on the Examiner.

4. Furthermore, the applicant's arguments directed to the restriction requirement stating that the inventions should be independent and distinct seems to be misplaced. According to MPEP 802.02, "restriction is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application." See also MPEP 802.01 (I)(II). As set forth in the previous restriction requirement and restated above, the examiner made a *prima facie* showing for restriction.

5. Additionally, this restriction was not directed to a national stage or 371 application. Therefore, the applicant's arguments directed towards "unity of invention" is inappropriate.

6. Applicant is reminded that, upon allowance, the first enabled method of using the claimed compound will be rejoined to the examined Invention. However, until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims should be maintained (*In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b), 1184 O.G. 86 March 26, 1996).

**The requirement is still deemed proper and is therefore made FINAL.**

7. Claims 64-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 17, 2006.

8. Claims 1-38, 41-44, 47-63 drawn to a non-therapeutic method of evaluating level of skin neurosensitivity and identifying persons having sensitive skin are being considered for examination in the instant application. Claims 39, 40, 45 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim.

9. Applicant's election of capsaicin as the species will be considered for examination.

***Specification***

10. The disclosure is objected to because of the following informalities:

A) Internet address:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, for example, page 14, line 1). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

B) The 'Brief Description of the Drawings' is missing from the Content of Specification. A reference to brief description of the drawing(s) as set forth in 37

CFR 1.74 (See MPEP § 608.01(f)) is required.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 – Written Description***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-38, 41-44, 47-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

13. Claims 1-38, 41-44, 47-63 are directed to a non-therapeutic method of evaluating skin neurosensitivity by application of (1) a peripheral nervous system stimulant, capsaicin (between $1 \times 10^{-6}$ % and $5 \times 10^{-4}$ %) comprising a physiologically acceptable aqueous alcohol vehicle to a skin area and recording the unattractive sensation (claims 1-2, 37-38, 41-55); (2) repeating (1) and increasing the concentration of the stimulant from (between $1 \times 10^{-6}$ % and $1 \times 10^{-4}$ %) until the individual perceives an unattractive sensation (claims 3-27); (3) vehicle followed by the stimulant and repeating the method as described in (2)

(claims 28-32); (4) vehicle on one side and vehicle plus stimulant on the opposite side of the skin, recording the unattractive sensation perceived by vehicle plus stimulant in relation to the vehicle on the opposite side and repeating the method of (2) (claims 33-36); (5) cosmetics by using the method as described in (1), (2), (3) and (4) above (claims 56-63). The claims further recite that the stimulants on topical application can induce the release of substance P or calcitonin-gene related peptide (CGRP (claim 14). The claims do not require that the stimulants possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature.

14. The specification teaches a non-therapeutic method of evaluating skin neuruosensitivity using peripheral nervous system stimulant (capsaicin) between $1 \times 10^{-6}$ % and $5 \times 10^{-4}$ % by weight relative to the weight of the composition, by gradually increasing the concentration of capsaicin by a factor of 1-10, and record the resulting unattractive sensation perceived (page 8, para 0035; page 13, para 0060; page 14, 15, paragraphs 0064 and 0066). Additionally, the specification teaches that symptoms producing the unattractive sensation or skin discomfort could be triggered by various factors such as environmental, emotional, physiological, dietary and topical applications (page 3, para 0012). However, the specification does not teach a relationship between the structure and function of the genus of peripheral nervous stimulants, cosmetics, vehicles and unattractive sensations encompassed by the claimed methods. The brief description in the specification of limited peripheral nervous system stimulants is

not adequate written description of an entire genus of functionally equivalent stimulants and cosmetics. There is also inadequate written description in the specification of an entire genus of methods of using a genus of vehicles and unattractive sensations. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of physical and/or chemical properties, functional characteristics of the peripheral nervous system stimulant for detecting neurosensitivity, structure/function correlation, or any combination thereof. However, in this case, the specification has not shown a relationship between the function, or properties of the claimed genus of peripheral nervous system stimulants, cosmetics, vehicles and unattractive sensations. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

15. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

16. With the exception of capsaicin as the peripheral nervous system stimulant, the skilled artisan cannot envision the peripheral nervous stimulants, cosmetics, vehicles and unattractive sensations of the encompassed methods and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of detecting skin neurosensitivity. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of using it. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

17. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the use of capsaicin.

18. Therefore, methods of using a specific cosmetic or capsaicin in a specific vehicle, and a specific unattractive sensation to detect skin neurosensitivity, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1-17, 20-27, 28-38, 41-44 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson and Perkins (Contact Dermatitis 45: 205-213, 2001 – cited by Applicant).

22. The claims recite a non-therapeutic method of evaluating skin neurosensitivity by application of a peripheral nervous system stimulant, capsaicin (between $1 \times 10^{-6}$ % and $5 \times 10^{-4}$ %) comprising a physiologically acceptable aqueous alcohol vehicle to a skin area, and recording the unattractive

sensation (see claims 1-6, 10-11, 13, 15-17, 20-21, 26-27, 29-32, 34-38, 41-44 and 52-55)

23. The claims also recite the method of evaluating skin neurosensitivity by repeating steps as described in above and further increasing the concentration of the stimulant from (between 1 x $10^{-6}$ % and 1 x $10^{-4}$ %), by a factor between 1 and 10 until the individual perceives an unattractive sensation, for example stinging, or until the maximum concentration is reached (see claims 3-6, 10-11, 13, 15-17, 20-21 and 26-27).

24. The claims recite the method of evaluating skin neurosensitivity by application of a vehicle, recording the unattractive sensation if present; if not proceeding the test using capsaicin, waiting for 30-360 seconds and repeating steps (see claims 29-32).

25. The claims recite the method of evaluating skin neurosensitivity by application of vehicle on opposite sides of the skin area, followed by recording the sensation and application of vehicle plus stimulant on one of the sides and repeating steps (see claims 34-36).

26. Robinson teaches a method of assessing skin irritation by using 100-10,000 μM capsaicin in 80% ethanol on filter papers onto the left and right forearm of subjects, waiting for 3 minutes and recording the sensory responses for both treatment and control skin areas, such as stinging, burning or itching (see figure 6, page 210; pages 206, 207, 211). Robinson further teaches that the concentration of capsaicin was increased by a factor between 1 and 10 (see

figure 5, page 210) until a moderate sensory response such as burning or itching was elicited. It is also well-established that capsaicin induces the release of substance P and CGRP when applied to skin (see for example, Roberts et al. (Agents Actions 37: 53-59, 1992, page 57). See also *In re Papesch, CCPA 137, USPQ 43* "a compound and all of its properties are inseparable".

27. Robinson does not teach the concentration of capsaicin to fall in the range of $1 \times 10^{-6}$% and $5 \times 10^{-4}$% or $1 \times 10^{-6}$% and $1 \times 10^{-4}$% by weight. Robinson does not teach a concentration of ethanol between 1% to 50%.

However, optimization within prior art conditions or through routine experimentation is obvious to one skilled in the art. As stated in MPEP 2144.05:

"The differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages". *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382; Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 UDPQ2d 1843 (Fed. Cir.).*

28. It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to determine the optimal ranges of capsaicin and alcohol content in the solution of the skin neurosensitivity testing method as taught by Robinson. The person of ordinary skill in the art would have been motivated to perform such tests on sensitive skin to assess the response to various products and chemicals (Robinson). The person of ordinary skill in the

art would have expected success because the method of testing sensory response to capsaicin was well established in the art at the time the invention was made.

29. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

30. Claims 56-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson and Perkins (Contact Dermatitis 45: 205-213, 2001), as applied to claims 1-17, 20-27, 28-38, 41-44 and 48-55 above and further in view of Hahn and Thueson (U.S. Patent No. 6,139,850, issued on 31 October 2000).

31. Claim 55-63 recites that the method of evaluating skin neurosensitivity as described above and further comprising a cosmetic product.

32. The teachings of Robinson are set forth above. Robinson does not teach the use of cosmetics as a function of skin neurosensitivity evaluation.

33. Hahn and Thueson teach skin irritation trials using capsaicin or lactic acid to determine skin sensitivity from the sting, burn or itch response. Hahn and Thueson also teach facial irritation trials using 10% benzoyl peroxide wash product ("Oxy 10") in subjects that reported a skin irritation response in the lactic acid irritation trial (column 20, lines 14-25; lines 61-65).

34. It would have been obvious to the person of ordinary skill in the art at the time the claimed invention was made to test the sensory responses of the skin to capsaicin as taught by Robinson in conjunction with various cosmetics as a

function of the skin neurosensitivity as taught by Hahn and Theuson. The person of ordinary skill in the art would have been motivated to additionally study the sensitivity of skin to cosmetics because environmental influences increase the skin's sensitivity to chemicals in topical products by reducing epidermal skin's barrier function, thereby increasing the permeability to chemical ingredients of cosmetics that would aggravate sensitivity (Hahn and Theuson column 3, lines 19-49). The person of ordinary skill in the art would have expected success because the method of evaluating skin neurosensitivity was well established in the art at the time the invention was made.

35. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

***Conclusion***

36. No claims are allowed.

37. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Rains C and Bryson HM. Drugs Aging 7: 317-328, 1995
(Reference showing the effects of topical capsaicin application)

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
August 15, 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER